

Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1-34 are pending in the application, with 1, 6, 7, 9, 11, and 13 being the independent claims. Claims 1, 6, 7, 9, 11, and 13 are sought to be amended. Support for the amendments to the claims is found in the specification *inter alia* at page 8, lines 21-26 and page 9, lines 4-7 and in the claims as originally filed. New claims 28-34 are sought to be added. Support for the new claims is found in the specification at page 17, lines 26-29. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Rejections under 35 U.S.C. § 112

Claims 1-27 have been rejected under 35 U.S.C. § 112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. (Office Action, page 2). Applicants respectfully traverse this rejection.

The Examiner is of the opinion that the specification does not describe a rigid polymer vehicle nor rigid polymer. (Office Action, page 2).

Applicants respectfully disagree. The claims as amended do not recite the phrases "rigid polymer vehicle" or "rigid polymer," rendering the rejection moot.

It is respectfully requested that the rejection of claims 1-27 under 35 U.S.C. § 112, first paragraph be withdrawn.

Rejections under 35 U.S.C. § 102

Claims 1-3, 5, 6, 21, and 22 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Goodson (U.S. Patent No. 4,892,736). (Office Action, page 2). Applicants respectfully traverse this rejection.

The Examiner is of the opinion that Goodson discloses a fiber comprising a polymer vehicle having incorporated therein one or more medicaments wherein the fiber has a size and shape suitable for placement in a root canal and that patentable weight is not given to the intended use of the fiber. (Office Action, page 2).

Applicants respectfully disagree. The claims as amended recite that the endodontic fiber is capable of being positioned deep within a root canal to enable the one or more medicaments incorporated therein to act locally at a site of deep bacterial infection. The capability of the fiber to be positioned deep within a root canal is more than an intended use of the fiber, it is a physical characteristic of the endodontic fiber that is a recited limitation of the claims and that must be described in the prior art in order for the prior art to be considered anticipatory.

Goodson does not describe a fiber that is capable of being positioned deep within a root canal to enable the one or more medicaments incorporated therein to act locally at a site of deep bacterial infection. Goodson discloses a periodontal fiber that has sufficient flexibility and formability to conform readily to a periodontal pocket, *i.e.*, soft

enough to bend around the perimeter of a tooth to make contact with the gum tissue to be treated. (Column 3, lines 29-33). The unsuitability of the Goodson fiber for endodontic use is evidenced by the necessity to spray the periodontal fibers disclosed in Goodson with a refrigerant spray in order to decrease the surface tackiness and increase the rigidity of the fibers. (Specification, page 13, lines 21-24). Accordingly, Goodson does not disclose every element recited in the claims and therefore cannot anticipate the claims.

It is respectfully requested that the rejection of claims 1-3, 5, 6, 21, and 22 over Goodson be withdrawn.

Claims 1-3, 5-14, and 21-26 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Miyazaki *et al.* (JP S63-303922). (Office Action, page 3). Applicants respectfully traverse this rejection.

The Examiner is of the opinion that Miyazaki *et al.* disclose a fiber comprising a polymer vehicle having incorporated therein one or more medicaments, wherein the medicament includes the antibiotic clindamycin or a combination of an antibiotic and an anti-inflammatory agent, as well as a method of obtaining the fiber, positioning the fiber in the root canal, and maintaining the fiber at the treatment site. (Office Action, page 3).

Applicants respectfully disagree. The claims as amended recite that the endodontic fiber is capable of being positioned deep within a root canal to enable the one or more medicaments incorporated therein to act locally at a site of deep bacterial infection. The capability of the fiber to be positioned deep within a root canal is a physical characteristic of the endodontic fiber that is a recited limitation of the claims

and that must be described in the prior art in order for the prior art to be considered anticipatory.

Miyazaki *et al.* are silent regarding the rigidity of the endodontic fibers or the capability of the fiber to be positioned deep within a root canal. Thus, Miyazaki *et al.* fail to disclose every limitation of the present claims.

The claims as amended further require that the endodontic fiber comprises a dose of said one or more medicaments of about 2.0 mg to about 5.0 mg per 10 mm of fiber. Miyazaki *et al.* fail to teach this limitation of the present claims as well. The only dosage disclosed in Miyazaki *et al.* is 180 µg sodium ampicillin in a fiber with a length of 5 mm, *i.e.*, 0.36 mg per 10 mm of fiber (page 132, column 1, second paragraph). This dose is about 10-fold lower than the required dose in the present claims. Accordingly, Miyazaki *et al.* fail to disclose every limitation of the present claims and therefore cannot anticipate the claims.

It is respectfully requested that the rejection of claims 1-3, 5-14, and 21-26 over Miyazaki *et al.* be withdrawn.

Rejections under 35 U.S.C. § 103

Claim 4 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Goodson in view of Damani (U.S. Patent No. 5,114,718). (Office Action, page 3). Applicants respectfully traverse this rejection.

The Examiner is of the opinion that Goodson does not disclose the medicament clindamycin but Damani teaches devices providing clindamycin as well as tetracycline,

and it would have been obvious to incorporate clindamycin into the fiber of Goodson since Damani discloses both as known antibiotics. (Office Action, pages 3-4).

Applicants respectfully disagree. As discussed above, Goodson fails to disclose endodontic fibers that are capable of being positioned deep within a root canal to enable the one or more medicaments incorporated therein to act locally at a site of deep bacterial infection as the periodontal fibers disclosed in Goodson do not have the necessary rigidity. Damani does not make up for the deficiency in Goodson. Damani discloses devices comprising medicaments for insertion into periodontal pockets. Damani is silent regarding the rigidity of the devices or the capability of inserting the devices deep into the root canal. Thus, the combination of Goodson and Damani does not teach every limitation of the present claims and therefore cannot render the claims obvious.

It is respectfully requested that the rejection of claim 4 over Goodson in view of Damani be withdrawn.

Claims 7-14 and 23-26 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Goodson. (Office Action, page 4). Applicants respectfully traverse this rejection.

The Examiner is of the opinion that Goodson does not show the step of the fiber in the root canal, but it would have been obvious to do so, since one would recognize that the fiber is of the size and characteristics sufficient for positioning in a root canal and Goodson shows a method of localized treatment within the oral cavity. (Office Action, page 4).

Applicants respectfully disagree. As discussed above, Goodson fails to disclose endodontic fibers that are capable of being positioned deep within a root canal to enable

the one or more medicaments incorporated therein to act locally at a site of deep bacterial infection as the periodontal fibers disclosed in Goodson do not have the necessary physical characteristics. This is evidenced by the necessity to spray the periodontal fibers disclosed in Goodson with a refrigerant spray in order to decrease the surface tackiness and increase the rigidity of the fibers. (Specification, page 13, lines 21-24). Thus, the Goodson fiber does not have characteristics sufficient for positioning deep in a root canal to treat a deep bacterial infection. Therefore, it would not have been obvious to one of ordinary skill in the art to use the Goodson fiber for endodontic purposes and attempt to position the fiber deep into the root canal.

It is respectfully requested that the rejection of claims 7-14 and 23-26 over Goodson be withdrawn.

Claims 15-20 and 27 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Goodson in view of Hoyt *et al.* (U.S. Patent No. 4,003,810). (Office Action, page 4). Applicants respectfully traverse this rejection.

The Examiner is of the opinion that Goodson does not disclose ethylene vinyl acetate (EVA) copolymer comprising less than about 20% vinyl acetate but Hoyt *et al.* disclose a fiber of EVA comprising 3 to 50 percent vinyl acetate, and that it would have been obvious to one of ordinary skill in the art to discover the optimum or workable ranges of a known material. (Office Action, page 4).

Applicants respectfully disagree. As discussed above, Goodson fails to disclose endodontic fibers that are capable of being positioned deep within a root canal to enable the one or more medicaments incorporated therein to act locally at a site of deep bacterial infection as the periodontal fibers disclosed in Goodson do not have the necessary

physical characteristics. Hoyt *et al.* do not make up for the deficiency in Goodson. Hoyt *et al.* disclose methods of hydrolyzing copolymers such as EVA without producing a yellow color in the hydrolysis product. (See abstract). While Hoyt *et al.* disclose that the EVA to be hydrolyzed may comprise 3-50% vinyl acetate (column 2, lines 45-50), they are silent regarding the physical properties of copolymers comprising different amounts of vinyl acetate. Hoyt *et al.* fail to provide any motivation to use the periodontal fibers described in Goodson for endodontic purposes and provide no teaching that altering the amount of vinyl acetate in EVA copolymers will result in a fiber that is suitable for insertion deep into root canals. Thus, the combination of Goodson and Hoyt *et al.* does not teach every limitation of the present claims and therefore cannot render the claims obvious.

It is respectfully requested that the rejection of claim 4 over Goodson in view of Hoyt *et al.* be withdrawn.

Claims 4, 15-20, and 27 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Miyazaki *et al.* in view of Goodson. (Office Action, pages 4-5). Applicants respectfully traverse this rejection.

The Examiner is of the opinion that Miyazaki *et al.* do not disclose EVA copolymer for use in fibers, but it would have been obvious to one of ordinary skill in the art to use the EVA fiber of Goodson in order to use a semipermeable biocompatible polymer. (Office Action, pages 4-5).

Applicants respectfully disagree. As discussed above, Goodson fails to disclose endodontic fibers that are capable of being positioned deep within a root canal to enable the one or more medicaments incorporated therein to act locally at a site of deep bacterial

infection as the periodontal fibers disclosed in Goodson do not have the necessary physical characteristics. There is no reason why one of ordinary skill in the art reading Goodson would substitute the soft and tacky EVA fiber taught by Goodson for the polymers disclosed in Miyazaki *et al.* for use in endodontic procedures as one would recognize the unsuitability of the Goodson fibers for insertion deep into root canals. Further, there is no teaching in either Goodson or Miyazaki *et al.* that altering the percentage of vinyl acetate in the EVA copolymer will produce a fiber that is suitable for deep penetration into root canals. Additionally, there is no teaching in either Goodson or Miyazaki *et al.* regarding the preparation of fibers comprising a dose of about 2.0 mg to about 5.0 mg of medicament per 10 mm of fiber. Thus, the combination of Miyazaki *et al.* and Goodson does not teach every limitation of the present claims and therefore cannot render the claims obvious.

It is respectfully requested that the rejection of claims 4, 15-20, and 27 over Miyazaki *et al.* in view of Goodson be withdrawn.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will

expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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